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IAP3 Rec'd PCT/PTO 1 MAR 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Toshihiro TANAKA et al.

Group Art Unit : Not Yet Assigned

Appl. No. : 10/523,723  
(U.S. National Stage of PCT/JP2003/010131)

I.A. Filed : August 8, 2003

Examiner : Not Yet Assigned

For : METHOD OF JUDGING INFLAMMATORY DISEASE



**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window, Mail Stop AMENDMENT  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir :

In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and §§1.97-1.98, Applicant hereby brings the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification, the International Search Report, and the International Preliminary Examination Report issued in connection with International Patent Application No. PCT/JP2003/010131, of which the present application is the U.S. National Stage Application. Copies of the International Search Report and the International Preliminary Examination Report were enclosed with the papers when entering the U.S. National Stage on February 7, 2005. The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the

documents cited therein. The following is a list of the documents cited in the above-noted documents:

- (1) BRESLOW, "Cardiovascular disease burden increases, NIH funding decreases," *Nature Medicine*, Vol. 3, No. 6, pp. 600-601 (1997). Applicants note that this document is cited on page 1 of the specification of the present application;
- (2) BRAUNWALD, "Shattuck Lecture – Cardiovascular Medicine at the turn of the millennium: Triumphs, concerns, and opportunities," *The New England Journal of Medicine*, Vol. 377, pp. 1360-1369 (1997). Applicants note that this document is cited on page 1 of the specification of the present application;
- (3) RISCH et al., "The Future of Genetic Studies of Complex Human Diseases," *Science*, Vol. 273, pp. 1516-1517 (1996). Applicants note that this document is cited on page 1 of the specification of the present application;
- (4) COLLINS et al., "Variations on a Theme: Cataloging Human DNA Sequence Variation," *Science*, Vol. 278, pp. 1580-1581 (1997). Applicants note that this document is cited on page 1 of the specification of the present application;
- (5) LANDER, "The New Genomics: Global Views of Biology," *Science*, Vol. 174, pp. 536-539 (1996). Applicants note that this document is cited on page 1 of the specification of the present application;
- (6) ROSS, "Atherosclerosis – An Inflammatory Disease," *The New England Journal of Medicine*, Vol. 340, No. 2, pp. 115-126 (1999). Applicants note that this document is cited on page 2 of the specification of the present application;

(7) OZAKI et al., "Functional SNPs in the lymphotoxin- $\alpha$  gene that are associated with susceptibility to myocardial infarction," *Nature Genetics*, Vol. 32, pp. 650-654 (2002). Applicants note that this document is cited on page 38 of the specification of the present application;

(8) IIDA et al., "Catalog of 258 single-nucleotide polymorphisms (SNPs) in genes encoding three organic anion transporters, three organic anion-transporting polypeptides, and three NADH: ubiquinone oxidoreductase flavoproteins," *Journal of Human Genetics*, Vol. 46, pp. 668-683 (2001).

Applicants note that this document is cited on page 24 of the specification of the present application;

(9) OHNISHI et al., "A high-throughput SNP genotyping system for genome-wide association studies," *Journal of Human Genetics*, Vol. 46, pp.471-477 (2001).

Applicants note that this document is cited on page 24 of the specification of the present application;

(10) YAMADA et al., "Association between a Single-Nucleotide Polymorphism in the Promoter of the Human Interleukin-3 Gene and Rheumatoid Arthritis in Japanese Patients, and Maximum-Likelihood Estimation of Combinatorial Effect That Two Genetic Loci Have on Susceptibility to the Disease," *American Journal of Human Genetics*, Vol. 68, pp. 674-685 (2001). Applicants note that this document is cited on page 25 of the specification of the present application;

(11) ALBERTELLA et al., "Characterization of a novel gene in the human major histocompatibility complex that encodes a potential new member of the I kappa B family of proteins," *Human Molecular Genetic*, Vol. 3, No. 5, pp. 793-799 (1994).

Applicants note that this document is cited on page 30 of the specification of the present application;

(12) MESSER et al., "Polymorphic Structure of the Tumor Necrosis Factor (TNF) Locus: An NcoI Polymorphism in the First Intron of the Human TNF- $\beta$  Gene Correlates with A Variant Amino Acid on Position 26 and a Reduced Level of TNF- $\beta$  Production," The Journal of Experimental Medicine, Vol. 173, pp. 209-219 (1991). Applicants note that this document is cited on page 30 of the specification of the present application;

(13) ANDREWS et al., "A rapid micropreparation technique for extraction of DNA-binding proteins from limiting numbers of mammalian cells," Nucleic Acids Research, Vol. 19, No. 9, p. 2499 (1991) Applicants note that this document is cited on page 30 of the specification of the present application;

(14) WARE et al., "The Ligands and Receptors of the Lymphotoxin System," Current Topics in Microbiology and Immunology, Vol. 198, pp. 175-218 (1995). Applicants note that this document is cited on page 31 of the specification of the present application;

(15) Japanese Laid-open Patent Publication No. 2002-136291, together with an English language abstract of the same Applicants note that this document is cited on page 3 of the specification of the present application;

(16) PADOVANI et al., "Gene Polymorphisms in the TNF Locus and the Risk of Myocardial Infarction," Thrombosis Research, Vol. 100. No. 4, pp. 263-269 (2000);

- (17) KESO et al., "Polymorphisms within the tumor necrosis factor locus and prevalence of coronary artery disease in middle-aged men," *Atherosclerosis*, Vol. 154, No. 3, pp. 691-697 (2001);
- (18) KOCH et al., "Interleukin-10 and tumor necrosis factor gene polymorphisms and risk of coronary artery diseases and myocardial infarction," *Atherosclerosis*, Vol. 159, No. 1, pp. 137-144 (2001); and
- (19) PANDEY et al., "TNF- $\alpha$  and TNF- $\beta$  Gene Polymorphisms in Systemic Sclerosis," *Human Immunology*, Vol. 60, pp. 1128-1130 (1999).

Applicants respectfully request that the Examiner consider the above material and cite the same. Copies of the above-noted documents (1)-(15) are attached hereto and copies of the documents (16)-(19) are not presently available. However, all of the above-noted documents are listed on the attached PTO-1449 Form. Further, copies of all of the documents should have been forwarded to the U.S. Patent and Trademark Office by the International Bureau.

The Examiner is requested to initial the appropriate spaces on the attached Form and to return a copy of the completed Form to Applicants with the next official communication in the present application.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material. However, if an Office Action on the merits has issued and is crossing this statement in the mail, the undersigned authorizes the Commissioner to charge any fee necessary for the consideration

of this statement, including any payment under 37 C.F.R. §1.17 (p) to Deposit Account No. 19-0089.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
Toshihiro TANAKA et al.



Bruce H. Bernstein  
Reg. No. 29,027

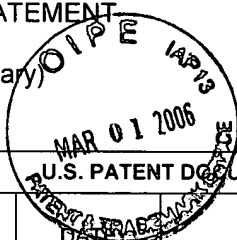
February 17, 2006  
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FORM PTO-1449

U.S. Department of Commerce  
Patent and Trademark OfficeAtty. Docket No.  
P26633Application No.  
10/523,723INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)

Applicant  
Toshihiro TANAKA et al.Filing Date  
August 8, 2003Group  
Not Yet Assigned

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
2002 - 1 3 6 2 9 1	05/14/02	JAPAN			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	BRESLOW, "Cardiovascular disease burden increases, NIH funding decreases," Nature Medicine, Vol. 3, No. 6, pp. 600-601 (1997).
2	BRAUNWALD, "Shattuck Lecture - Cardiovascular Medicine at the turn of the millennium: Triumphs, concerns, and opportunities," The New England Journal of Medicine, Vol. 377, pp. 1360-1369 (1997).
3	RISCH et al., "The Future of Genetic Studies of Complex Human Diseases," Science, Vol. 273, pp. 1516-1517 (1996).
4	COLLINS et al., "Variations on a Theme: Cataloging Human DNA Sequence Variation," Science, Vol. 278, pp. 1580-1581 (1997).
5	LANDER, "The New Genomics: Global Views of Biology," Science, Vol. 174, pp. 536-539 (1996).
7	ROSS, "Atherosclerosis - An Inflammatory Disease," The New England Journal of Medicine, Vol. 340, No. 2, pp. 115-126 (1999).
8	OZAKI et al., "Functional SNPs in the lymphotoxin- $\alpha$ gene that are associated with susceptibility to myocardial infarction," Nature Genetics, Vol. 32, pp. 650-654 (2002).
9	IIDA et al., "Catalog of 258 single-nucleotide polymorphisms (SNPs) in genes encoding three organic anion transporters, three organic anion-transporting polypeptides, and three NADH: ubiquinone oxidoreductase flavoproteins," Journal of Human Genetics, Vol. 46, pp. 668-683 (2001).
10	OHNISHI et al., "A high-throughput SNP genotyping system for genome-wide association studies," Journal of Human Genetics, Vol. 46, pp. 471-477 (2001).
11	YAMADA et al., "Association between a Single-Nucleotide Polymorphism in the Promoter of the Human Interleukin-3 Gene and Rheumatoid Arthritis in Japanese Patients, and Maximum-Likelihood Estimation of Combinatorial Effect That Two Genetic Loci Have on Susceptibility to the Disease," American Journal of Human Genetics, Vol. 68, pp. 674-685 (2001).
12	ALBERTELLA et al., "Characterization of a novel gene in the human major histocompatibility complex that encodes a potential new member of the I kappa B family of proteins," Human Molecular Genetic, Vol. 3, No. 5, pp. 793-799 (1994).
13	MESSER et al., "Polymorphic Structure of the Tumor Necrosis Factor (TNF) Locus: An NcoI Polymorphism in the First Intron of the Human TNF- $\beta$ Gene Correlates with A Variant Amino Acid on Position 26 and a Reduced Level of TNF- $\beta$ Production," The Journal of Experimental Medicine, Vol. 173, pp. 209-219 (1991).

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Department of Commerce  
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Atty. Docket No.  
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Application No.  
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(Use several sheets if necessary)

Applicant  
Toshihiro TANAKA et al.

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August 8, 2003

Group	Not Yet Assigned
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## U.S. PATENT DOCUMENTS

EXAMINER  
INITIAL

DOCUMENT NUMBER

DATE \_\_\_\_\_

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CLASS

SUBCLASS

FILING DATE  
IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER

DATE \_\_\_\_\_

COUNTRY

CLASS

SUBCLASS

TRANSLATION  
YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

14	ANDREWS et al., "A rapid micropreparation technique for extraction of DNA-binding proteins from limiting numbers of mammalian cells," <i>Nucleic Acids Research</i> , Vol. 19, No. 9, p. 2499 (1991)
15	WARE et al., "The Ligands and Receptors of the Lymphotoxin System," <i>Current Topics in Microbiology and Immunology</i> , Vol. 198, pp. 175-218 (1995).
16	English Language Abstract of JP 2002-136291.

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.